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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,790	11/12/2003	Gerald B. Pier	B0801.70255US01	5867
23628 7590 05/15/2007 WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206			EXAMINER DEVI, SARVAMANGALA J N	
			ART UNIT 1645	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/713,790	Applicant(s) PIER ET AL.	
	Examiner S. Devi, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2, 4-25 and 42 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-25 and 42 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **RESPONSE TO APPLICANTS' AMENDMENT**

### **Applicants' Amendment**

1) Acknowledgment is made of Applicants' amendment filed 03/22/07 in response to the non-final Office Action mailed 12/18/06. With this, Applicants have amended the specification and the claims.

### **Status of Claims**

2) Claims 3, 26-41 and 43-81 have been canceled via the amendment filed 03/22/07.

Claims 1, 2, 4-6, 8, 9, 11, 12, 14, 16, 17, 22-24 and 42 have been amended via the amendment filed 03/22/07.

Claims 1, 2, 4-25 and 42 are pending and are under examination.

### **Prior Citation of Title 35 Sections**

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

### **Prior Citation of References**

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Objection(s) Withdrawn**

5) The objection to the specification made in paragraph 7 of the Office Action mailed 12/18/06 is withdrawn in light of Applicants' amendment to the specification.

### **Rejection(s) Moot**

6) The provisional rejection of claim 3 made in paragraph 8 of the Office Action mailed 12/18/06 under the judicially created doctrine of obviousness-type double patenting over claim 63 of the co-pending application 10/713,790, is moot in light of Applicants' cancellation of the claim.

7) The rejection of claim 3 made in paragraph 12 of the Office Action mailed 12/18/06 under 35 U.S.C § 102(b) as being anticipated by McKenney *et al.* (*Infect. Immun.* 66: 4711-4720, October 1998 - Applicants' IDS), is moot in light of Applicants' cancellation of the claim.

### **Rejection(s) Withdrawn**

- 8)** The provisional rejection of claims 1, 2, 6, 8, 9, 11, 14, 19 and 20 made in paragraph 8 of the Office Action mailed 12/18/06 under the judicially created doctrine of obviousness-type double patenting over claim 63 of the co-pending application 10/713,790, is withdrawn in light of the new rejection set forth below.
- 9)** The rejection of claim 4 made in paragraph 10(a) of the Office Action mailed 12/18/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 10)** The rejection of claim 6 made in paragraph 10(b) of the Office Action mailed 12/18/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 11)** The rejection of claim 11 made in paragraph 10(c) of the Office Action mailed 12/18/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 12)** The rejection of claim 12 made in paragraph 10(d) of the Office Action mailed 12/18/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 14)** The rejection of claim 42 made in paragraph 10(e) of the Office Action mailed 12/18/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 15)** The rejection of claim 14 made in paragraph 10(f) of the Office Action mailed 12/18/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 16)** The rejection of claims 16 and 17 made in paragraph 10(g) of the Office Action mailed 12/18/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.
- 17)** The rejection of claim 22 made in paragraph 10(h) of the Office Action mailed 12/18/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

- 18)** The rejection of claim 23 made in paragraph 10(i) of the Office Action mailed 12/18/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 19)** The rejection of claim 24 made in paragraph 10(j) of the Office Action mailed 12/18/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 20)** The rejection of claim 24 made in paragraph 10(k) of the Office Action mailed 12/18/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 21)** The rejection of claim 25 made in paragraph 10(l) of the Office Action mailed 12/18/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.
- 22)** The rejection of claims 1, 2, 4-16 and 18-24 made in paragraph 12 of the Office Action mailed 12/18/06 under 35 U.S.C § 102(b) as being anticipated by McKenney *et al.* (*Infect. Immun.* 66: 4711-4720, October 1998 - Applicants' IDS), is withdrawn in light of Applicants' amendment to the claims and/or the base claim(s). A modified rejection is set forth below to cover the claims as amended. Applicants' arguments with respect to this rejection have been considered, but are moot in view of the withdrawal of the rejection and the new ground(s) of rejection set forth below.
- 23)** The rejection of claim 25 made in paragraph 14 of the Office Action mailed 12/18/06 is rejected under 35 U.S.C § 103(a) as being unpatentable over McKenney *et al.* (*Infect. Immun.* 66: 4711-4720, October 1998 - Applicants' IDS) as applied to claims 22 and 21, and further in view of Pier *et al.* (US 20020119166 – Applicants' IDS), is withdrawn in light of Applicants' amendment to the base claim. A modified rejection is set forth below to cover the claim as depends from an amended claim. Applicants' arguments with respect to this rejection have been considered, but are moot in view of the withdrawal of the rejection and the new ground(s) of rejection set forth below.

### **Double Patenting Rejection**

- 24)** Claims 1, 2, 6, 8, 9, 11, 14, 19 and 20 are provisionally rejected under the judicially created

doctrine of obviousness-type double patenting over claim 63 of the co-pending application 09/771,003. Claim 18 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 67 of the co-pending application 09/771,003. Although the conflicting claims are not identical, they are not patentably distinct from each other because the product of claims 63 and 67 of the above-identified co-pending application falls within the scope of the above-identified claims. The portions of the disclosure from the co-pending application that provide support for the isolated PS/A polysaccharide composition having a molecular weight of >100,000 Daltons and being greater than 92% pure as claimed, do not exclude, but expressly encompass an isolated sterile beta-1,6-glucosamine polymer composition differing in the degree of acetate substitution (inclusive of less than 50% acetate substitution). See the structures disclosed on pages 3 and 5; and sections [0067] and [0129] of the published version (US 20020119166) of the co-pending application 09/771,003.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Rejection(s) under 35 U.S.C § 112, Second Paragraph**

**25)** Claims 1, 2, 4-25 and 42 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claims 16 and 17 have improper antecedent basis in the limitation: 'the carrier compound'. Claims 16 and 17 depend from claim 15, which recites 'a carrier', but not 'a carrier compound'. For proper antecedent basis, it is suggested that Applicants replace the above-identified limitation with the limitation --the carrier--.

(b) Claims 1 and 2 appear to be redundant in the limitations: 'less than 50% of glucosamine amino groups are substituted with acetate ..... less than 50% of the R groups are – NH-CO-CH<sub>3</sub>'.

(c) Claim 2 is vague and indefinite in the limitation: 'having a length of at least two monomeric units ..... wherein n is an integer that is at least four', because it is unclear how a polymer having a minimum length of two monomeric units can have an n that is four. Does the recited polysaccharide comprise a minimum of two monomeric units or a minimum of four monomeric units'?

(d) Claim 42 is vague, indefinite, and has improper antecedent basis in the limitation: 'the isolated polysaccharide of claim 1'. Claim 42 depends from claim 1, which is not directed to 'an isolated polysaccharide', but to a composition.

(e) Claim 23 is indefinite and/or appears to lack proper antecedent basis in the limitation: 'or linker joined to the carrier compound'. Claim 23 depends from claim 22, which already recites 'the linker joined to a carrier compound'. Does it mean that the 'linker joined to the carrier compound' as recited in claim 23 is different from the one recited in the base claim 22?

(f) Claim 23 is indefinite and/or appears to lack proper antecedent basis in the limitation: 'only one of X1, X2, X3, X4, X5 or X6'. Claim 23 depends directly from claim 22 and indirectly from claim 21. Claim 21 already recites X1, X2, X3, X4, X5 or X6'. Does it mean that the 'only one of X1, X2, X3, X4, X5 or X6' recited in claim 23 is different from the one recited in the base claim 21?

(g) Analogous rejection and criticism apply to the limitation 'only one of Y1, Y2 or Y3' in claim 24.

(h) Claim 21 is indefinite and confusing with regard to the recited structure. Claim 21 depends from claim 1. With regard to X1, X2, X3, X4 and X5 being H and Y1 and Y3 being OH, it is unclear how claim 21 is further limiting, because the structure recited in claim 1 already has H at sites recited in claim 21 as X1, X2, X3, X4 and X5, and OH at sites recited as Y1 and Y3.

(i) In claim 14, for the purpose of distinctly claiming the subject matter, it is suggested that Applicants replace the phrase: 'within the composition has a purity selected from the group consisting of ..... 99% pure' with the phrase --is at least 90% pure, at least 95% pure, at least 97% pure, or at least 99% pure--.

(j) In the last line of claims 1 and 2, for clarity for the purpose of distinctly claiming the subject matter, it is suggested that Applicants replace the limitation 'having' with the limitation --has--.

(k) Claims 4-25 and 42, which depend directly or indirectly from claim 1, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

### **Rejection(s) under 35 U.S.C § 102**

**26)** Claims 1, 2, 4-16, 18-24 and 42 are rejected under 35 U.S.C § 102(b) as being anticipated by McKenney *et al.* (*Infect. Immun.* 66: 4711-4720, October 1998 - Applicants' IDS) (McKenney

*et al.*, 1998) as evidenced by Joyce *et al.* (*Carbohydr. Res.* 338: 903-922, 2003), McKenney *et al.* (*J. Biotechnol.* 83: 37-44, 2000 - Applicants' IDS) (McKenney *et al.*, 2000), and Maira-Litran *et al.* (*Infect. Immune.* 73: 6752-6762, 2005).

It is noted that the inventor Gerald B. Pier is one of the co-authors of each of the references cited above.

McKenney *et al.* (1998) taught a PS/A composition (i.e., vaccine) comprising or consisting of an isolated and purified large molecular weight beta-1,6-glucosamine polysaccharide substituted with zero to 33% acetate (i.e., less than 50%). The composition further contains phosphate buffered saline (i.e., pharmaceutically acceptable carrier) and is filter-sterilized. The polysaccharide contained glucosamine as the single sugar component, and therefore is expected to be at least 90% pure. See first full paragraph on page 4714; and paragraph bridging pages 4712 and 4713. The molecular weight of the polysaccharide is >250,000 kDa, and therefore would be expected to contain at least two or four monomeric units of the structure recited in claims 2 and 21, wherein n is at least 6, wherein X1, X2, X3, X4, X5 and X6 is H, and Y1, Y2 and Y3 is OH, wherein one of the X1, X2, X3, X4, X5 or X6, or Y1, Y2 or Y3 in the monomeric units is conjugated to the adjacent saccharide unit(s), i.e., a carrier compound. See abstract. Although the PS/A polysaccharide is said to be additionally succinate-substituted (see abstract), that the prior art PS/A is the same as the later identified PNAG, i.e., poly-N-acetyl-beta-(1-6)-glucosamine, which was 'mistakenly identified' in the art as PNSG, i.e., poly-N-succinyl beta-1-6 glucosamine, is inherent from the teachings of the prior art in light of what is known in the art. For instance, McKenney *et al.* (2000) identified the staphylococcal PS/A to be the same material as the staphylococcal PNSG (see first full paragraph in right column on page 42 of McKenney *et al.* (2000)), which PNSG was later identified in the art as PNAG that was 'mistakenly identified' as PNSG (see paragraph bridging pages 6752 and 6753 of Maria-Litran *et al.*, 2005)). It is well known in the art that the misidentified N-succinyl in McKenney's (1998) PS/A was 'an analytical artifact' (see abstract of Joyce *et al.*), and that McKenney's (1998) identification of N-succinylation was 'incorrect' and was 'due to a misinterpretation of analytical data resulting from hydrolysis artifacts' (see paragraph bridging the two columns on page 904 of Joyce *et al.*)

Claims 1, 2, 4-16, 18-24 and 42 are anticipated by McKenney *et al.*



### Rejection(s) under 35 U.S.C § 103

**27)** Claims 17 and 25 are rejected under 35 U.S.C § 103(a) as being unpatentable over McKenney *et al.* (*Infect. Immun.* 66: 4711-4720, October 1998 - Applicants' IDS) (McKenney *et al.*, 1998) as applied to claims 15, 1, 22 and 21 above, and further in view of Pier *et al.* (US 20020119166 – Applicants' IDS).

The teachings of reference of Pier *et al.* is applied in this rejection because it qualifies as prior art under subsection (e) or (a) of 35 U.S.C. § 102 and accordingly is not disqualified under U.S.C. 103(a).

The teachings of McKenney *et al.* (1998) are explained above which do not expressly disclose that the at least four monomeric beta-1,6-glucosamine polysaccharide is conjugated to a carrier compound that is not an N-acetyl beta 1-6 glucosamine.

However, conjugating an isolated staphylococcal poly-beta-1-6-N-acetylglucosamine to a carrier compound including a carrier protein such as BSA or KLH, a peptide, or a lipid using conjugation methods well known in the art was routine and conventional in the art at the time of invention for the purpose of enhancing its immunogenicity in a species of animal to be immunized. For example, see sections [0028], [0085], [0086], and [0089] of Pier *et al.*

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to conjugate McKenney's (1998) isolated beta-1,6-glucosamine polysaccharide to an art-known carrier protein such as KLH, BSA, or a peptide using an art-known conjugation technique as taught by Pier *et al.* to produce the instant invention with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to produce the instant invention for the expected benefit of enhancing the immunogenicity of McKenney's (1998) isolated beta-1,6-glucosamine polysaccharide in a species of animal to be immunized as taught by Pier *et al.*

Claims 17 and 25 are *prima facie* obvious over the prior art of record.

### Objection(s)

**28)** Claim 9 is objected for the incorrect limitation 'at least-10,000' (see line 4) as opposed to the correct limitation --at least 10,000 Daltons--.


### Remarks

- 29) Claims 1, 2, 4-25 and 42 stand rejected.
- 30) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted to fax number (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.
- 31) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).
- 32) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

May, 2007

  
S. DEVI, PH.D.  
PRIMARY EXAMINER